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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/611,835	07/07/00	STOCKWELL B	50164/002002

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EXAMINER	
KOROMA, B	
ART UNIT	**PAPER NUMBER**
1627	2

DATE MAILED: 12/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/611,835	STOCKWELL ET AL.	
	Examiner	Art Unit	
	BARBA M KOROMA	1627	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2000* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-63* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Please note: In an effort to enhance communication with our customers and reduce processing time, a dedicated Fax machine is in place to receive your responses. The Fax number is 703 305 3704. A Fax cover sheet is attached to this office action for your convenience. We encourage your participation in this pilot program. If you have any questions or suggestions please contact Jyothsna Venkat, PhD, Supervisory Patent Examiner, at: jyothsna.venkat@uspto.gov or 703 308 2439. Please limit the use of this dedicated Fax number to responses to Written Restrictions. Thank you in advance for allowing us to enhance our customer service.

Election/Restriction

Claims 1-63 are currently pending in this application.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-24, 28-44, 48-63, drawn to a method of screening a two-entity or higher order combinations for biological activity, classified in class 435, subclass 183.

II. Claims 25 and 45, drawn to a method for treating a disease, classified in class 514, subclass 2+.

III. Claims 26, 27, 46 and 47, drawn to a compound and composition, classified in classes 424 and 530, various subclasses.

Inventions I and II are drawn to independent and/or distinct methods or processes which exhibit different modes of operation, functions, and effects (MPEP § 806.04, MPEP § 808.01). In the instant case, a method of screening a two-entity or higher order combination for biological activity, and a method of treating a disease, are different inventions with separate objectives, entailing different steps and producing different outcomes or effects. Art anticipating or rendering obvious invention I would not anticipate or render obvious invention II. Each would support separate inventions.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to produce an infinite possibility of combinations, and the product or combination(s) as claimed can be generated by another and materially different process such as rational computer modeling.

Inventions II and III are related as process of use and product made. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the method of using the product as claimed can be practiced with another materially different product such as any synthesized organic compound, for example, tetracycline, or (2) the

product as claimed can be used in a materially different process such as developing a kit for immunoassay.

Because the inventions:

a. Have divergent subject matter,

b. Have acquired a separate status in the art as shown by their different classification,

c. Have different and separately burdensome manual and/or computer-aided bibliographical searches,

therefore, they are deemed distinct inventions and restriction for examination purposes as indicated above is proper.

Election of Species

Claims 1-24, 28-44, and 48-63, drawn to a method of screening are generic to a plurality of disclosed patentably distinct species comprising: i) unspecified combinations of entities, ii) unspecified test elements, and iii) unspecified detection methods.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of:

i). combination entity such as a purified compound, providing a structural formula thereof; a peptide, providing the sequence of the active motif thereof, an oligonucleotide, providing the base sequence thereof; an ion, providing the symbol and valence thereof; or radiation, providing the energy magnitude thereof;

ii). a single test element such as a Hela cell; and

iii). a single method of detection such as a fluorogenic assay complemented by fluorescence microscopy.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

All inquiries regarding this case should be directed to ***Barba M. Koroma***. This examiner can normally be reached at: **703 305 1915, *9:00am to 5:00pm, Monday through Friday.***

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, PhD, can be reached at: 703 308 2439. The phone number for the organization where this application or proceeding is assigned is: 703 308 2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is: 703 308 1235.

J. Venkat

DR. JYOTHSNA VENKAT PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600